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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/405,050      | 09/27/1999  | YEHUDA SHOENFELD     | ZAP-1CIPCONC        | 9070             |

7590

07/09/2004

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EXAMINER

NAVARRO, ALBERT MARK

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1645

DATE MAILED: 07/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/405,050

Applicant(s)

SHOENFELD ET AL.

Examiner

Mark Navarro

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 and 22-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 22-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

Applicants response filed March 25, 2004 has been received and entered.

Accordingly claims 1-11 and 22-29 remain pending in the instant application.

#### ***Claim Rejections - 35 USC § 112***

1. The rejection of claims 1-11 and 22-29 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, a new matter rejection is maintained.

Applicants are asserting that the specification sets forth that lymphoma, among certain other types of cancer is "particularly prone to metastasize." (Page 2, lines 6-8). Applicants further assert that IVIG acts as an anti-metastatic agent resulting in the reduction of tumor colony numbers. Applicants further assert that Examples 1-5, demonstrate the effectiveness of the claimed invention and were carried out in mouse models of metastatic cancer. Applicants finally assert that Examples 6-7 support the use of IVIG in patients with metastatic disease.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants asserting that the specification sets forth that lymphoma, among certain other types of cancer is "particularly prone to metastasize." However, this does not provide support for specifically inhibiting metastasis in only mammals which have

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active metastasis. Simply put, if the lymphoma is “particularly prone to metastasize” why wouldn’t one of skill in the art treat every lymphoma to prevent metastasis, even before metastasis has been demonstrated to be actively occurring?

Second, Applicants assert that IVIG acts as an anti-metastatic agent resulting in the reduction of tumor colony numbers. However, Applicants are reminded that the prior art has disclosed administering IVIG to individuals with lymphomas. (See Chapel et al, Morell et al, and Besa et al of record). The sole reason that these rejections have been withdrawn is Applicants amendment to recite “wherein the mammal has metastatic lymphoma.” It is this limitation of active metastasis, which attempts to exclude prior art, that must find support in the originally filed specification.

Third, Applicants assert that Examples 1-5, demonstrate the effectiveness of the claimed invention and were carried out in mouse models of metastatic cancer. However, Applicants are respectfully directed back to the claims. Claim 1 recites “wherein the mammal has metastatic lymphoma.” Each of Examples 1-5 deals with melanoma, a tumor of melanocytes. Lymphomas are a tumor of the lymphoid tissue. Accordingly, any Examples dealing with a different type of tumor do not provide support for lymphomas.

Finally, Applicants assert that Examples 6-7 support the use of IVIG in patients with metastatic disease. However, Example 6 is purely prophetic. Further there is no mention of determining if metastasis is active prior to administering IVIG. Applicants are again reminded that patients with lymphomas have received IVIG in the prior art. In order to now claim administering IVIG to patients with active metastasis, this limitation

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must find support in the originally filed specification. As for Example 7, this again is an example directed towards melanoma, which as explained above is a different type of tumor than the now claimed metastatic lymphoma.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

### ***Double Patenting***

2. The rejection of claims 1-11 and 22-29 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,965,130 is maintained.

It is noted that Applicants have indicated a willingness to submit a terminal disclaimer upon an indication that all other rejections are withdrawn. However, until a terminal disclaimer is made of record, this rejection is maintained for reasons of record.

3. The rejection of claims 1-11 and 22-29 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,562,902 is maintained.

It is noted that Applicants have indicated a willingness to submit a terminal disclaimer upon an indication that all other rejections are withdrawn. However, until a terminal disclaimer is made of record, this rejection is maintained for reasons of record.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro  
Primary Examiner  
July 7, 2004